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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/234,847 01/22/99 LEVY

S PKZ-013CP

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HM22/0606

EXAMINER

BADIO, B

ART UNIT

PAPER NUMBER

1616

DATE MAILED:

06/06/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/234,847

Applicant(s)

Levy et al.

Examiner

Barbara Badio

Group Art Unit

1616



☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-29 is/are pending in the application.

Of the above, claim(s) 2, 4-6, and 8-28 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1, 3, 7, and 29 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 8

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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First Office Action on the Merits

Election/Restriction

1. *See page 19* Claims 2, 4-6 and 8-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 11.

Note: Claims 2 and 4-6 stand withdrawn because applicant's elected species, 9-t-butyl-6-deoxy-5-acetylcarbonyloxytetracycline, is not encompassed by the definition of compounds of formula I. That is, the definition of R_2 as defined by claim 2 does not include an acyloxy group or an acylcarbonyloxy group as recited by claim 6 and the elected species.

Claims 1, 3, 7 and 29 will be examined to the extent they read on the elected species and obvious variants thereof.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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3. Claims 1, 3 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Bernardi et al. ('942).

Bernardi et al. teach a generic group of 5,9-substituted tetracycline derivatives, including 9-t-butyl-alpha-6-deoxy-5-hydroxytetracycline (see the entire article, especially col. 1, formula II and col. 10, example 10). The reference teaches the compounds are useful as chemotherapeutic agents and in the preparation of 7-substituted tetracycline derivatives (col. 1, lines 60-64). The compounds and compositions taught by the reference are encompassed by the instant claims.

4. Claims 1 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Bernardi et al. ('384).

Bernardi et al. teach a generic group of 5,9-substituted tetracycline derivatives, including 9-methylthiomethyl-alpha-6-deoxy-5-hydroxytetracycline and 9-methyl-alpha-6-deoxy-5-hydroxytetracycline (see the entire article, especially page 1, formula I; page 4, examples 8 and 9). The reference teaches the compounds are of therapeutic interest (page 1, col. 1, lines 10-14). The compounds and compositions taught by the reference are encompassed by the instant claims.

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Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 3, 7 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernardi et al. ('942).

Bernardi et al. teach a generic group of 5,9-substituted tetracycline derivatives, including 9-t-butyl-alpha-6-deoxy-5-hydroxytetracycline (see the entire article, especially col. 1, formula II and col. 10, example 10). The reference teaches the compounds are useful as chemotherapeutic agent and in the preparation of 7-substituted tetracycline derivatives (col. 1, lines 60-64).

The instant claims differ from the reference by reciting additional tetracycline derivatives not taught by or exemplified by the reference. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including that of the instant claims, because an ordinary artisan would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as the genus as a whole.

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7. Claims 1, 3, 7 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernardi et al. ('384).

Bernardi et al. teach a generic group of 5,9-substituted tetracycline derivatives, including 9-methylthiomethyl-alpha-6-deoxy-5-hydroxytetracycline and 9-methyl-alpha-6-deoxy-5-hydroxytetracycline (see the entire article, especially page 1, formula I; page 4, examples 8 and 9). The reference teaches the compounds are of therapeutic interest (page 1, col. 1, lines 10-14). The compounds and compositions taught by the reference are encompassed by the instant claims.

The instant claims differ from the reference by reciting additional tetracycline derivatives not taught or exemplified by the reference. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including that of the instant claims, because an ordinary artisan would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as the genus as a whole.

Allowable Subject Matter

8. Applicant's elected species, 9-t-butyl-6-deoxy-5-acetylcarbonyloxytetracycline, is allowable.

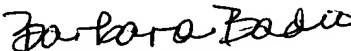
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Telephone Inquiry Contacts

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara Badio whose telephone number is (703) 308-4595. The examiner can normally be reached between 7:30 am and 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, José Dees, can be reached on (703) 308-4628. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.


Barbara Badio
Art Unit 1616

June 5, 2000